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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
02/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,628	ANDERSON ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-23 and 34-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-23 and 34-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment and Request for Continued Examination filed on 11/14/2008.

Claims 19-20 and 23 have been amended.

Claims 1-10, 12, 16-18 and 24-33 have been canceled.

Claims 34-51 have been added.

Claims 19-23 and 34-51 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/14/2008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. The term "a major fraction" in claim 36 is a relative term which renders the claim indefinite. The term "a major fraction" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope

of the invention. The term a major fraction of activated carbon means to what extend of the total amount or what quantity of activated carbon is present in the container of the system.

4. The term "a lightly adhering" in claim 49 is a relative term which renders the claim indefinite. The term "a lightly adhering" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Because a lightly adhering impermeable membrane may be very thin or transparent or thick impermeable separator membrane situated between anti-abuse layer and abusable substance.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 10, 12 and 16-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcenyac et al (US 2004/0146547) **are withdrawn** in view of applicant's amendment to claims.

However, upon further consideration a new ground(s) of rejection is made as follows.

8. Claims 19-23 and 34-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcenyac et al (US 2004/0146547) and Granger et al (US 5,149,538) in view of Church (6,660,901).

Applicant's claims are drawn to a system for skin-worn transdermal patch devices containing abusable substances, a layer containing anti-abuse substance such as antagonists, irritants or activated carbon and closure means for closing said container.

Marcenyac et al discloses an article (a transdermal patch) includes a reservoir housing a dye and/or medicament inactivating agent (which would read on anti-abuse substance) in communication with the reservoir that is released when the reservoir is opened or revealed (see 0009). And further, the article may include a pocket (which would read on flexible pouch) having a sealable opening and formed between first and second portions of the opposite side of the inner layer, wherein the opening is optionally sealed by a flap covered at least in part by a permanent pressure and/or heat sensitive adhesive (see 0014). And also the disposing of a transdermal patch includes placing a transdermal patch within the article, sealing the patch (which would read on adhesive seal) within a pocket

of the article, such that the article releases the detection material and/or inactivating agent when the reservoir is opened and thus the article prevents of hinders misuse of the active agent contained in the transdermal dosage form (see 0022). And further, article includes a medicament layer containing an opiate e.g. fentanyl; the inactivating agent include the rat or human mu-opioid receptor; opioid-neutralising antibodies; narcotic antagonists such as naloxone, naltrexne and nalmedrne; dysphoric or irritating agents such as scopolamine, ketoamine, atropine or mustard oils or any combinations thereof (see 0112 and 0114). And in practice, if the active agent in a transdermal patch to be disposed of by placing it in the present article were an opioid, the inactivating agent renders the active agent unavailable through inactivation, such as for example chemical inactivation or alteration of the receptor binding site of the active agent; biounavailability; physical unavailability; loss of appeal of the active agent to the abuser, such as for example, an inactivating agent which creates an intolerably bad taste or an intolerable reaction such as extreme nausea or the like; or something similar thereto. One or more inactivating agent(s) may be used (see 0099). And further discloses that it is known in prior art (US 5,804,215) to Cubbage et al. relates to disposal system for a transdermal patch comprising a pouch for transport of the patch and disposal system encapsulates a trasndermal patch and prevents access to it.

Marcenyac et al. teaches use of various anti- abuse substances directly related to effective in preventing abuse, were an opioid, the inactivating agent could be a chemical or denaturing agent that would alter residual opioid

molecules in the dosage form and make them inactive (0100). Since the inactivating agents is directly related to anti-abuse substance, and the prior art teaches the same subject matter (disposable of transdermal patch containing residual or unused opioid in a separate pouch) by similar process, it is examiner's position that, in the absence of evidence to the contrary, a suitable specific anti-abuse substance is also either anticipated by Marcenyac, or obviously provided by practicing the invention of prior art. It should be noted that where claimed and prior art products are shown to be identical or substantially identical in composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. See MPEP § 2112.01.

Granger discloses a transdermal adhesive patch comprising opioid such as buprenorphine or salts and one or more anit-abusable substance in an effective amount to substantially attenuate the euphorigenic effect of the opioid, and it is releasable from the dosage form upon being ingested or substantially immersed in water, alcohol or other solvent and barrier means which separates said antagonist substance from said opioid, said barrier means being impermeable to said opioid and to said antagonist substance, which would read on lightly adhering impermeable separator membrane (col. 3 line 25-40). Additional disclosure includes that the impermeable barrier separates the opioid in the dosage form from the antagonist substance to prevent any adverse chemical reactions or ion exchanges between the opioid and the antagonist, and to prevent release of the antagonist unless the dosage form is ingested or

immersed in water, alcohol or other solvent. If ingested or solvent extracted, the antagonist substance substantially attenuates the euphorigenic effect of the opioid, thereby reducing the tendency for misuse and abuse of the dosage form (col. 2 line 55-64).

Marcenyac and Granger meet the claim limitation as discussed above but fail to include particularly activated carbon as anti-abuse substance therein.

Church discloses a patch for topical application to the skin includes a charcoal based composition for the purpose of adsorbing toxins, bacteria, fungus, carcinogens, and other harmful pathogens. And charcoal composition is comprised of activated charcoal combined with one or more host materials to produce a solid gel-like substance or otherwise formed as a layer for application to the impervious backing sheet. In one embodiment, the charcoal composition is contained within a porous container or envelope (col. 2 lines 36-55). Additional disclosure includes that that charcoal skin patch is adapted to reduce swelling of the skin by adsorbing excess tissue fluid and products of inflammation (col. 2 line 28-32).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate activated carbon/charcoal as an anti-abusable substance into the Marcenyac and Granger transdermal adhesive patch thereby reducing the tendency for misuse and abuse of the dosage form. The person of ordinary skill in the art would have been motivated to make those modification, because Marcenyac teaches that the inactivating agent may be released when the dosage form is handled in a particular manner, such as whein

it is folded, bent, squeezed with sufficient force, peeled from the skin, or the like, or if the dosage form is abused, such as for example, is chewed, soaked, subjected to extraction, smoked, or the like, to inactivate any residual active agent when the dosage form is discarded (0110). Therefore, one of ordinary skill in the art would have had a reasonable expectation of success because both Marcenyac and Church teaches a transdermal adhesive patch that can be used in the same field of endeavor, such as for example chemical inactivation or alteration of the receptor binding site of the active agent; biounavailability; physical unavailability; loss of appeal of the active agent to the abuser, such as for example, an inactivating agent which creates an intolerably bad taste or an intolerable reaction such as extreme nausea or the like; or something similar thereto.

Response to Arguments

9. Applicant's arguments filed 11/14/2008 have been fully considered but they are not persuasive. Applicant argues that Marcenyac et al fails to teach or suggest the use of binding or adsorption agent which is active and operates on contact to prevent subsequent specific solvent extraction. This is not found persuasive, since the Marcenyac reference teaches various inactivating agent (which would read on binding or adsorption agent) when contacted with or a medicament or active agent to be placed in the article, renders the active agent unavailable through inactivation, such as for e.g chemical inactivation or alteration of the receptor binding site of the active agent; biounavailability;

physical unavailability (0099). Similarly, the inactivating agent could be a non-opioid with distressing or dysphoric properties if absorbed that made abuse unpeeling (0100). Further the inactivating agent may be released when the dosage form is handled in a particular manner, squeezed with sufficient force, or if the dosage form is abused, such as for example, is chewed, soaked, subjected to extraction, smoked, or the like. Thus, this article could be used, for example, to inactivate any residual active agent when the dosage form is discarded (0110). It is well established that the claims are given the broadest reasonable interpretation during examination in light of the supporting disclosure as it would be interpreted by one of ordinary skill in the art, In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023,1027-28 (Fed. Cir. 1997); In re Am. Acad. of ScL Tech. Ctr., 367 F.3d 1359,1364, [70 USPQ2d 1827] (Fed. Cir. 2004). Further, it has been held that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); Chef America, Inc. v. Lamb-Weston, Inc., 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004). In the present case, the inactivating agents disclosed by the prior art reads on the claimed binding or adsorption agent, in absence of claiming specific characteristics of the binding or adsorption agent.

Applicant also argues that the binding agent containing reservoir and drug containing reservoir are not isolated from the skin and thereby the binding agent will absorb organic materials from the skin and become useless for inactivating the drug after disposable. Applicant is correct that the binding agent containing

reservoir is not isolated from the skin and medicament containing reservoir, but as disclosed, a transdermal dosage form (Fig. 3) having a transfer side and an opposite side, and optionally an adhesive disposed on the periperimeter of the transfer side. The transfer side comprises a first and second region (reservoirs), wherein the regions are separated from one another by a membrane or impermeable barrier, so that the inactivating agent would not mix with the active agent therein. And further, the inactivating agent comes in contacted with the medicament only when the dosage form is handled in a particular manner, such as when it is folded, bent, squeezed with sufficient force, peeled from the skin, or the like. Thus, the reservoir containing the inactivating agent is still active to bind or adsorb the residual amounts of an abusable substance when the dosage form is discarded.

Applicant further argues that Marcenyac reference there is no teaching of a separately attached device that withdrawn a separation membrane with removal of the delivery patch. This is not found persuasive, since the reference teaches the article that includes a pocket having a sealable opening and formed between first and second portions of the opposite side of the inner layer, wherein the opening is optionally sealed by a flap covered a least in part by a permanent pressure and/or heat sensitive adhesive. And further, the article may also include a peelable release layer covering the adhesive. Since the reference teaches the same desired function of safely disposing the transderaml patch, and the article comprising an outer layer and an inner layer which are joined by an adhesive covering a first portion of the inner layer, and the inner and outer layers of the

reference is capable of performing the same function, then it meets the claims. The art as a whole teaches a disposable article to prevent the misuse of a transdermal dosage form for the transdermal delivery of opioids. Obviousness does not require absolute predictability.

Conclusion

1. No claims are allowed at this time.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr